

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Ming Bo Wang et al.) Group Art Unit: 1638
Application No.: 10/780,638) Examiner: Russell Kallis
Filed: February 19, 2004) Confirmation No.: 2125
For: EFFICIENT GENE SILENCING IN PLANTS USING SHORT DSRNA SEQUENCES)))

REPLY TO SECOND RESTRICTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated September 7, 2006, setting forth a revised requirement for restriction, Applicants make the following election with traverse.

The restriction requirement set forth in the Office Action dated July 11, 2006 has been vacated. As a result, Applicants' election with traverse filed August 9, 2006 was of no effect and is withdrawn.

The present Office Action sets forth a requirement for restriction between groups A, B or C set forth on page 3 as directed to the promoter of a plant gene encoding U6snRNA, U3snRNA, and 7SL RNA, respectively. The Office Action further requires an election from among groups I – VIII directed to recited portions of SEQ ID NOS:1 to 8, respectively.

The restriction requirement is traversed, because the claims are not drawn to the subject matter of the groups which have been set forth in the Office Action. Rather, the claimed invention is directed to a method for reducing the expression of a gene of interest in a plant cell comprising providing a chimeric gene to the plant cell as recited in claim 1, and to

the chimeric gene itself, and plants and pant cells comprising the chimeric gene. The individual promoter sequences to which the Office proposes limiting the application represent only a portion of the chimeric genes that are used in method as a whole.

Furthermore, it must be noted that the promoters among which the applicant has been required to elect are not novel in themselves. Indeed the specification provides examples of many Poll III promoters have been isolated, listing the promoters by name and database accession number. For example, see paragraphs [0026] to [0029]. See also the attached Information Disclosure Statement, which includes example entries from the NCBI database. It is the whole combination of the promoters with the other elements of the recited chimeric genes and their use in the method in plants which is both novel and un-obvious. The claims must be examined as a whole and not with respect to individual parts. As the recited promoters form only a part of the invention, there can be no serious burden in examining the reasonable number of recited alternative features of the preferred embodiments of the claimed invention together.

The Office Action indicates that "This requirement is not to be construed as a requirement for an election of species." Applicants respectfully submit that this aspect of the restriction requirement is also improper and is therefore further traversed.

The present election must be treated at least as prescribed in Manual of Patent Examination Procedure § 803.02, 808.04(d) and 809. Claim 1 is generic to Groups A, B and C and to Groups I – VIII as defined in Manual of Patent Examination Procedure § 808.04(d) and links these groups as defined in Manual of Patent Examination Procedure § 809. Claim 2 recites a Markush grouping as defined in Manual of Patent Examination Procedure § 803.02 of promoter sequences that have been divided into Groups A, B and C. Claim 3 recites a Markush grouping of the sequences that have been divided into Groups I – VIII. The

procedures prescribed in the Manual of Patent Examination Procedure §§ 803.02, 806.04(d) and 809 all lead to the same conclusion. The election herein must be treated as an election of species for examination purposes. After the elected species are found allowable, then examination must be expanded to encompass the generic claims and the reasonable number of species recited in the Markush style claims. 37 C.F.R. § 1.141 provides that an allowable generic claim may link a reasonable number of species embraced thereby.

The Office has alleged that "each of the nucleic acid sequences is not a member of a single structurally and functionally related genus." The Office has further alleged "the polynucleotides are each unique molecules with different chemical, structural, and functional features." Applicants submit that this cannot be a *per se* rule. In the present case, the recited Poll III promoters share common chemical, structural and functional features.

The different exemplified promoters, be it the three groups or the 8 specific nucleotides, are characterized by being recognized by a DNA dependent RNA polymerase 3 (POLIII) and are further of the subtype of POLIII recognized promoters wherein all required cis-elements are located upstream of the RNA transcription initiation site (type 3). See paragraph [0026].

SEQ ID NOS: 1 and 2 are examples of a 7SL-2 gene transcribing POLIII type 3 promoter; SEQ ID NOS:3, 4, 7 and 8 are examples of a U3snRNA transcribing POLIII type 3 promoter; SEQ ID NOS:5 and 6 are examples of a promoter U6snRNA transcribing POLIII type 3 promoter.

Thus, chemically, each of the molecules is related as being a nucleic acid, sharing a well recognized common backbone structure. Functionally, the promoters are related in being promoter sequences and in being recognized by polymerase III. Both of these common functionalities necessitate that the recited promoters share common structural features, for

example the conserved upstream sequence element (USE) and TATA-like box, which are separated by a further conserved spacing. A table is attached as Exhibit A which demonstrates clearly the existence of conserved sequence and structural features of Poll III promoters such as those recited in the claims. See, also Waibel et al., *Nucleic Acid Research*, 18:3451-58, 1990; and Waibel et al., *Nature*, 346:199-202, 1990, submitted herewith.

Furthermore, it will be clear from the specification that SEQ ID NO 1 and 2 are related in sequence to each other as SEQ ID NO 2 comprises SEQ ID NO 1 with an additional 86 nucleotides. Similarly, SEQ ID NOS 3 and 4 are related (SEQ ID NO 4 comprises SEQ ID NO 3 with an additional 136 nucleotides) and SEQ ID NOS 5 and 6 are related (SEQ ID NO 6 comprises SEQ ID NO 5 with an additional 20 nucleotides).

Therefore, it is simply not true that the recited promoters are not members of a single structurally related genus. Accordingly, the election below is at least entitled to be treated as an election of species as set forth in the Manual of Patent Examination Procedure.

The Examiner is also reminded of the policy of the Office set forth in the Manual of Patent Examination Procedure § 803.04, most recently reaffirmed in the Fifth Revision of the Eighth Edition, published August 2006, which states as follows:

[T]he *>Director< has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction.

The Examiner has not adduced any of the reasons for making exceptions to this policy provided for in Manual of Patent Examination Procedure § 803.04.

For at least the foregoing reasons, the restriction requirement is improper and should be withdrawn. At the very least, the election should be treated as an election of species, with Claim 1 being treated as a generic claim, for which purpose Applicants elect Groups B and III. A Notice of Allowance is believed to be next in order and such action is earnestly requested.

By:

Respectfully submitted,

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Date: November 7, 2006

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